

§ 520.2582

6.25 grams of phenothiazine, and the equivalent of 20.0 grams of piperazine base (as piperazine dihydrochloride).

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Special considerations.* Labeling shall bear the following statements: The drug is a cholinesterase inhibitor. Do not use this product in horses simultaneously with, or within 2 weeks before or after treatment with, or exposure to, neuromuscular depolarizing agents (e.g., succinylcholine) or to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) *Conditions of use—(1) Amount.* 18.2 milligrams of trichlorfon, 12.5 milligrams of phenothiazine, and 40.0 milligrams of piperazine base per pound of body weight.

(2) *Indications for use.* For horses for removal of bots (*Gastrophilus nasalis*, *Gastrophilus intestinalis*), large strongyles (*Strongylus vulgaris*), small strongyles, large roundworms (ascarids, *Parascaris equorum*), and pinworms (*Oxyuris equi*).

(3) *Limitations.* Mix powder and vial contents together in warm water to form suspension. Administer by stomach tube. Do not fast horses before or after treatment. Treatment of mares in late pregnancy is not recommended. Surgery or any severe stress should be avoided for at least 2 weeks before or after treatment. Do not administer to sick, toxic, or debilitated horses. Not to be used in horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 2757, Jan. 21, 1983]

§ 520.2582 Triflupromazine hydrochloride tablets.

(a) *Specifications.* Each tablet contains either 10 milligrams or 25 milligrams of triflupromazine hydrochloride.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs and cats to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require

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the aid of a tranquilizer, antiemetic, or preanesthetic.¹

(2) The drug is administered orally to dogs and cats at a dosage level of 1 to 2 milligrams per pound of body weight daily; an initial dosage at the 2-milligrams level is suggested followed by daily doses at the 1-milligram level. Frequently, the drug may be withdrawn after 4 to 5 days, with drug effect continuing after withdrawal.¹

(3) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.2604 Trimeprazine tartrate and prednisolone tablets.

(a) *Specifications.* Each tablet contains: trimeprazine tartrate, 5 milligrams; and prednisolone, 2 milligrams.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered orally to dogs for the relief of itching regardless of cause; reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular and nonspecific. It is also used in dogs as adjunctive therapy in various cough conditions including treatment of “kennel cough” or tracheobronchitis, bronchitis including allergic bronchitis, in tonsillitis, acute upper respiratory infections and coughs of nonspecific origin. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.¹

(2) The drug is administered orally at an initial dosage level of ½ tablet twice daily to dogs weighing up to 10 pounds, one tablet twice daily to dogs weighing 11 to 20 pounds, two tablets twice daily to dogs weighing 21 to 40 pounds, and three tablets twice daily to dogs weighing over 40 pounds. After

4 days, the dosage is reduced to approximately $\frac{1}{2}$ the initial dosage or to an amount just sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained.¹

(3) Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea.¹

(4) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.¹

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.2605 Trimeprazine tartrate and prednisolone capsules.

(a) *Specifications.* Each capsule contains 3.75 milligrams of trimeprazine in sustained released form (as the tartrate) and 1 milligram of prednisolone (capsule no. 1) or 7.5 milligrams of trimeprazine in sustained release form (as the tartrate) and 2 milligrams of prednisolone (capsule no. 2).

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer either capsule orally once daily to dogs as follows:

Animal weight (pounds)	Number of capsules per dose	
	Capsule No. 1	Capsule No. 2
Up to 10	1
11 to 20	2	1
21 to 40	4	2
Over 40	6	3

(2) *Indications for use.* For the relief of itching regardless of cause, reduction

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

of inflammation commonly associated with most skin disorders of dogs such as eczema caused by internal disorders, otitis, and dermatitis (allergic, parasitic, pustular, and nonspecific). It is also used in dogs as adjunctive therapy in various cough conditions including treatment of “kennel cough” or tracheobronchitis, bronchitis including allergic bronchitis, tonsillitis, acute upper respiratory infections, and coughs of nonspecific origin. The product may also be administered to dogs suffering from acute or chronic bacterial infections, provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.

(3) *Limitations.* After 4 days, reduce dosage to one-half the initial dose or to an amount sufficient to maintain remission of symptoms. Dosages in individual cases may vary and should be adjusted until proper response is obtained. Do not use the drug in cases of viral infections involving corneal ulceration or dendritic ulceration of the cornea. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 19367, Apr. 29, 1983, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.2610 Trimethoprim and sulfadiazine tablets.

(a) *Specifications.* Each tablet contains 30 milligrams (5 milligrams of trimethoprim and 25 milligrams of sulfadiazine), 120 milligrams (20 milligrams of trimethoprim and 100 milligrams of sulfadiazine), 480 milligrams (80 milligrams of trimethoprim and 400 milligrams of sulfadiazine) or 960 milligrams (160 milligrams of trimethoprim and 800 milligrams of sulfadiazine).

(b) *Sponsor.* See Nos. 000061 and 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs where systemic antibacterial action against sensitive organisms is required, either alone or as an